PDBP
Parkinson's Disease Biomarkers Program

* Required fields

Informed Consent and Enrollment

*Name of Site: _____

*Type of Visit: _____
e.g. Screening, Baseline, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months, 42 months, 48 months, 54 months, 60 months.

*Date of Visit: _____

*GUID: _____

*Age of Subject (years and months): _____

Subject ID: _____

1.* Was informed consent obtained?

☐ Yes ☐ No (Skip to 2)

Date of Consent: ____/_____/20_____
m m d d y y y y

2.* Was the participant/subject enrolled into the study?

☐ Yes ☐ No (Skip to 3)

Date Enrolled: ____/_____/20_____
m m d d y y y y

3.* Was the participant/subject randomized?

☐ Yes ☐ No ☐ Not applicable

Date Randomized: ____/_____/20_____
m m d d y y y y

Informed Consent and Enrollment CRF Module Instructions

General Instructions

It is important to collect the date of certain study milestones, such as informed consent, study enrollment and randomization, from both an administrative and human subjects' protection standpoint.

For some studies it will be possible to enroll participants/subjects without informed consent, if a waiver of consent is granted. An IRB may waive the requirements to obtain informed consent provided the IRB finds and documents that:

- the research involves no more than minimal risk to the participants/subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the participants/subjects;
- the research could not practically be carried out without the waiver or alteration;
- and whenever appropriate, the participants/subjects will be provided with additional pertinent information after participation.

For studies where participants/subjects are not randomized to different intervention groups, the randomization data elements are not applicable and should not be collected.

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- **Was informed consent obtained?** – Choose one. If YES, record date informed consent was obtained.
- **Date of consent -** Record the date (and time) the informed consent form is signed. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
- **Was the participant/subject enrolled into the study?** – Choose one. If YES, record the date enrolled.
- **Date enrolled -** Record the date (and time) the participant/subject is enrolled in the study. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
- **Was the participant/subject randomized?** – Choose one. If YES, record the date randomized. This CDE should only be included on the CRF if the study is a randomized clinical trial. Otherwise, it can be removed.
- **Date randomized -** Record the date (and time) the participant/subject is randomized to a treatment or control group. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database. This CDE should only be included on the CRF if the study is a randomized clinical trial. Otherwise, it can be removed.